

II. REMARKS

A. Status of the Claims

Claims 1 to 9 and 12 to 19 are currently pending. Claims 10, 11 and 20 to 22 were previously withdrawn from consideration. Claims 23 to 42 were previously canceled. Claims 1, 8, 9, 12, and 16 to 19 have been amended. Support for the amendments can be found throughout the specification, e.g., page 6, lines 5 to 28; page 7, lines 16 to 22. It is respectfully submitted that no new matter was added by virtue of this amendment.

Reconsideration of the application is respectfully requested.

B. Claim Objections

Claim 9

In the Office Action, claim 9 was objected to for reciting “and/or 25 endonucleases.”

Applicants respectfully submit that claim 9 has been amended to recite “and/or endonucleases” as suggested by the Examiner in the Office Action.

Therefore, Applicants respectfully request that the objection to claim 9 be withdrawn.

Claim 19

In the Office Action, claim 19 was objected to “because a claim to a method does not properly depend from a step recited in another claim to a method.” Claim 19 was also objected to under 37 CFR 1.75(c) as being in improper form “because a multiple dependent claim may refer to more than one claims only in the alternative.”

Amended claim 19 recites: “A method according to claim 1 wherein the pre-treatment comprises removing cell bound contaminating nucleic acids from the sample by exposing nucleic acid in the cells and then removing the nucleic acid, and wherein nucleic acid is removed using the pre-treatment step comprising treating the sample to preferentially remove or inactivate nucleic acids that are free or substantially free from other cell components.”

Applicants respectfully submit that claim 19 has been amended to refer to the complete method of claim 1. In light of the amended claim 19, the objection to claim 19 under 37 CFR 1.75(c) as being in improper form is moot.

Therefore, Applicants respectfully request that the objection(s) to claim 19 be withdrawn.

B. Claim Rejections under 35 USC §112

Claims 1 to 9 and 12 to 19

In the Office Action, claims 1 to 9 and 12 to 19 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete “for omitting essential steps, such omission amounting to a gap between the steps. The omitted steps are the steps of analyzing the nucleic acid.

Amended independent claim 1 recites: “A method of pretreating a nucleic acid sample obtained from a site, prior to analysis of the sample comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids originating from the site.”

Applicants respectfully submit that independent claim 1 has been amended to refer to a method of pretreating a nucleic acid sample. In light of the amended claim 1, the objection(s) to claims 1 to 9 and 12 to 19 under 35 U.S.C. 112 as omitting steps of “analyzing the nucleic acid” is moot.

Therefore, Applicants respectfully request that the objection(s) to claims 1 to 9 and 12 to 19 under 35 U.S.C. 112 be withdrawn.

Claims 3, 4 and 14

In the Office Action, claims 3, 4, and 14 were rejected as being indefinite over the recitation of “particularly well adapted for amplification via PCR.” The Office Action stated that “this phrase is not clearly defined in the specification.” See Office action at page 5, lines 6 to 7.

Applicants respectfully draw the Examiner’s attention to the present specification at page 5, lines 14 to 20 wherein “particularly well adapted for amplification via PCR” is defined as being “when the contaminating nucleic acid is free or substantially free from other cell components.”

Therefore, Applicants respectfully request that the objection(s) to claims 3, 4, and 14 under 35 U.S.C. 112 be withdrawn.

Claims 8 and 9

In the Office Action, claims 8 and 9 were rejected as being indefinite over the recitation of “selected from the group comprising.”

Amended claim 8 recites “a method according to claim 7 wherein the pre-treatment is one or more treatments selected from the group consisting of : (i) enzymic treatments; (ii) physical treatments; and (iii) chemical treatments.”

In light of the amended claim 8, the objections to claims 8 and 9 under 35 U.S.C. §112 are moot . Therefore, Applicants respectfully request that the objection to claim 8 and claim 9, which is dependent on claim 8, under 35 U.S.C. 112 be withdrawn.

Claim 12

In the Office Action, claim 12 was rejected as being indefinite over the recitation of “wherein the method of analyzing the nucleic acid sample is PCR, mitochondrial DNA sequence...and low copy number PCR.”

Amended claim 12 recites “a method according to claim 1 wherein the method of pretreating a nucleic acid sample is PCR, mitochondrial DNA sequencing, single nucleotide polymorphism (SNP) analysis or low copy number PCR.”

Applicants respectfully submit that claim 12 has been amended to refer to the distinct methods of pretreating a nucleic acid sample in the alternative as suggested by the Examiner. In light of amended claim 12, Applicants respectfully request that the objection to claim 12 under 35 U.S.C. 112 be withdrawn.

Claim 16

In the Office Action, claim 16 was rejected as being indefinite over the recitation of “nucleic acid is bacteria.”

Amended claim 16 recites “a method according to claim 15 wherein the contaminating nucleic acid is from bacteria engineered to contain at least one multicopy plasmid comprising at least one amplicon.”

Applicants respectfully request that the objection to claim 16 under 35 U.S.C. 112 be withdrawn in view of amended claim 16, which currently recites that the “contaminating nucleic acid is from bacteria.”

Claims 17 to 19

In the Office Action, claims 17 to 19 were rejected as being indefinite over the recitation of “the nucleic acid in the cells.”

Amended claim 17 recites “a method according to claim 13 wherein the cell bound contaminating nucleic acid is removed by exposing nucleic acid in the cells and then removing the nucleic acid.”

Amended claim 18 recites “a method according to claim 17 wherein nucleic acid is exposed by lysing the cells.”

Amended claim 19 recites “a method according to claim 1 wherein the pre-treatment comprises removing cell bound contaminating nucleic acids from the sample by exposing nucleic acid in the cells and then removing the nucleic acid, and wherein nucleic acid is removed using the pre-treatment step comprising treating the sample to preferentially remove or inactivate nucleic acids that are free or substantially free from other cell components.”

In light of amended claims 17 to 19, Applicants respectfully request that the objection to claims 17 to 19 under 35 U.S.C. 112 be withdrawn.

C. Claim Rejections under 35 USC §102

Rejection under 35 USC 102(b) - Walker (EP 0585660)

Claims 1 to 9 and 12 were rejected under 35 USC 102(b) as being anticipated by Walker (EP 0585660).

Walker discloses a method of decontaminating the products of a nucleic acid amplification reaction (amplicons) from a nucleic acid sample with exonucleases. See Walker, paragraph [0001] lines 5 to 6.

Independent claim 1 as currently amended recites “a method of pretreating a nucleic acid sample obtained from a site, prior to analysis of the sample comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids originating from the site.

Applicants respectfully direct the Examiner’s attention to the definition for the claimed “contaminating nucleic acids” at page 5, lines 5 to 8 of the detailed description of the present invention:

"For the purposes of the present invention the phrase "contaminating nucleic acid/s" is defined as nucleic acid that has been introduced to a site or a sample to confound future analysis of target nucleic acids present at the site or in the sample."

Walker does not show or teach contaminating nucleic acids introduced to a site to confound future analysis of target nucleic acids. Instead, Walker provides for a method to remove single stranded amplicon contamination from prepared nucleic samples. Walker is concerned only with laboratory-derived contamination of prepared nucleic acid samples. Walker does not provide methods or procedures to address pre-existing amplicon, or similar contamination of evidentiary tissue samples that are introduced to a site or to a sample to confound future analysis, as identified in the current application. Therefore, Walker does not show or teach "a method of pretreating a nucleic acid sample obtained from a site, prior to analysis of the sample comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids originating from the site" as recited in independent claim 1 of the present application.

Furthermore, the description of the methods at paragraph [0020] of Walker describes how separation into two or more portions upon entry into the laboratory could be used as a means to determine whether a result was genuine or a false positive caused by contamination. Such a method would be unable to determine the presence of contamination in samples exposed to the contaminant prior to it being received at the laboratory, an essential feature of the current invention, and would, invariably give an incorrect result with suitably contaminated samples. The methods described in Walker would also be detrimental to the detection and/or removal of amplicon contamination where the DNA profile was determined by the use of single nucleotide polymorphisms as used in forensic studies. This is because the conditions required to reliably degrade any contaminating amplicons would also invariably (and completely) degrade any sample nucleic acids, again rendering the determination of a valid DNA profile impossible.

In contrast to the current application, the method described in Walker describes only the use of single-strand specific exonucleases (e.g. exonuclease VII, exonuclease I, DNA polymerase 3'-5' exonuclease activity) as agents for the removal of contaminating amplicons. Such enzymes would have limited utility in preventing contamination of the type identified in the current application as this amplicon contamination could quite commonly be double stranded in nature and therefore unaffected by the single stranded exonucleases described in Walker.

Therefore, Walker does not teach or show "a method of pretreating a nucleic acid sample obtained from a site, prior to analysis of the sample comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids originating from the site" as recited in independent claim 1 of the present application.

Withdrawal of the rejection to independent claim 1, along with its dependents claims 2 to 9 and 12, under 35 U.S.C. §102(b) is respectfully requested.

Rejection under 35 USC 102(b) - Miwa (U.S. Patent 4,514,502)

Claims 1 to 3, 5, 6, 8, 9 and 12 to 19 were rejected under 35 USC 102(b) as being anticipated by Miwa (U.S. Patent 4,514,502).

Miwa discloses a composite plasmid which is capable of propagating in *Coryneform* glutamic acid-producing bacteria. See Miwa, col. 1, lines 6 to 9.

Independent claim 1 as currently amended recites "a method of pretreating a nucleic acid sample obtained from a site, prior to analysis of the sample comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids originating from the site."

The definition for the claimed "contaminating nucleic acids" is discussed above.

Miwa (US 4,514,502) does not show or teach contaminating nucleic acids introduced to a site to confound future analysis of target nucleic acids. Miwa treats a sample of laboratory-prepared plasmid DNA with RNase I to remove any contaminating RNA which

remains from an earlier bacterial lysis step. See Miwa, col.6, lines 56 - 68 through col. 7, lines 1 - 6 and 48 - 51. Therefore, Miwa is concerned only with laboratory-derived contamination of prepared nucleic acid samples. Miwa does not provide methods or procedures to address pre-existing amplicon, or similar contamination of evidentiary tissue samples that are introduced to a site or to a sample to confound future analysis. Therefore, Miwa does not teach or show “a method of pretreating a nucleic acid sample obtained from a site, prior to analysis of the sample comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids originating from the site” as recited in independent claim 1 of the present application.

Withdrawal of the rejection to independent claim 1, along with its dependents claims 2 to 3, 5, 6, 8, 9 and 12 to 19, under 35 U.S.C. §102(b) is respectfully requested.

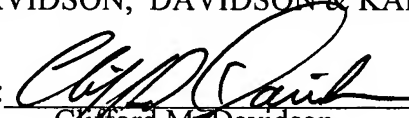
III. CONCLUSION

A check in the amount of \$60.00 is enclosed for the fee due under 37 C.F.R. § 1.17(a)(1) for a one-month extension of time from September 11, 2007 to October 11, 2007. It is believed that no additional fees are due for this submission. In the event that any fee is deemed due, the Commissioner is hereby authorized to charge such fee to Attorney Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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